

**APPENDIX 2**  
**(Gervais Declaration)**

I hereby certify that this correspondence is being deposited with the United States Postal Services on the date set forth below as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date of Signature  
and Deposit: 10/12/06 Michael A. Hengeman

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Duchesnay Inc.  
Serial No.: 10/611,803  
Filed: July 1, 2003  
Title: PHARMACEUTICAL DOSAGE FORM BEARING PREGNANCY-FRIENDLY  
INDICIA  
Examiner: Hawes, Pili Asabi

---

**DECLARATION UNDER 37 CFR 1.132**

---

Dear Sir:

I, Eric Gervais, of the City of Laval, Canada, being duly sworn, **MAKE OATH AND SAY AS FOLLOWS:**

1. This Declaration sets forth my opinion relating to this matter and the basis for my opinion.
- I. **EXPERIENCE AND QUALIFICATIONS**
2. I have been the Executive Vice-President of Duchesnay Inc. since 1994.
3. Created before 1970 to distribute over-the-counter and prescription medications to Quebec pharmacies, Duchesnay Inc. underwent a change of orientation around 1991, becoming the first pharmaceutical company to dedicate itself exclusively to the pregnant women and their newborn, to ensure that expecting women who require pharmacological treatments for pre-existing or pregnancy-related diseases have

access to proper counselling and to medications that are proven safe for them and for their newborns. Since then, Duchesnay has been evolving as a research-based pharmaceutical company with the vision to improve women's quality of life of women during pregnancy and lactation while reducing the number of birth defects and impacts on their newborns.

4. Thus, I have more than 12 years of experience in leading a company dedicated to pregnant women's health, as well as in associated research and development.
5. I am also an inventor in several patents and patent applications in the name of Duchesnay Inc.
6. I am one of the inventors of United States Patent Application 10/611,803.

**II. DICLECTIN®**

7. Diclectin® comprises doxylamine succinate and pyridoxine hydrochloride as active ingredients. In Canada, it is the only anti-nauseant and anti-vomiting medication specifically indicated, prescribed and labelled for the management of NVP (nausea and vomiting of pregnancy) at any stage of pregnancy. It is sold in the form of unit bottles comprising 100 tablets each.
8. Diclectin® was first launched on the Canadian market in 1975.
9. Throughout the recent years, the percentage of yearly increase of sales of unit bottles of Diclectin® was generally decreasing from year to year in Canada as a whole, as per the below table. Such tendency was not expected to change.

1998-1999	1999-2000	2000-2001	2001-2002
18%	11.7%	9.4%	8.6%

10. It is to be noted that, since Diclectin® is the only available prescription medicament for NVP in Canada, Duchesnay is the only company in this particular field. Thus an

increase in the sales of unit bottles of Diclectin® is directly linked to an increased number of pregnant women buying these bottles.

11. A Diclectin® with a graphical indicia of a pregnant woman applied on each tablet was launched in the Canadian market around the end of November 2002. The application of the indicia constituted the only change to the medicament. Absolutely no specific marketing was associated with this change.
12. Very surprisingly, we, at Duchesnay, observed that the sales of unit bottles of Diclectin® in 2003 for Canada increased by 14.8% with regard to those of 2002, which constituted an exceptionally high increase, as compared to the increases observed over the preceding years.
13. That increase was the average of significant individual increases in all territories of Canada (British Columbia, Alberta, Saskatchewan+Manitoba, Ontario, Quebec, Atlantic provinces), whether or not medical representatives were circulating therethrough.
14. For example, there were at that time four medical representatives in Ontario, where the sales increase observed between 2002 and 2003 was of 17.73%, and there was absolutely no medical representative in Saskatchewan+Manitoba, where the sales increase observed between 2002 and 2003 was of 17.8%.
15. By contrast, no increase in the natality rate was observed in Canada in 2002-2003, to which the increased number of sales could have been attributed.
16. Thus, in my opinion, nothing else than the application of a graphical representation of a pregnant woman on each tablet of Diclectin® has caused this surprising increase in sales.
17. Since Diclectin® is prescribed by physician, the increase in sales is most probably due to greater amounts of prescription refills.

**VI. CONCLUSION****18. In my opinion:**

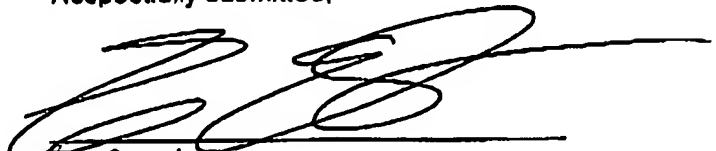
18.1 The exceptional increase of sales of Diclectin® unit bottles observed in 2003 constituted an unexpected commercial success for the medicament.

18.2 The commercial success of Diclectin® observed in 2003 is solely due to the application of pregnancy-friendly indicia on each Diclectin® tablet at the end of 2002.

19. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that wilful false statements and the like made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such wilful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

Respectfully submitted,

11/02/2006  
Date

  
Eric Gervais